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Comparative Effectiveness Research Priorities in the Recovery Act

www.hhs.gov/recovery/programs/cer/index.html

These facts must be considered by the Committee (see **www.bioclonetics.com** for more details):

1) There exists today an alternative to chronic chemotherapy (which is results in treatment toxicity), the treatment now being used to treat patients with HIV

2) It is imperative that this new alternative be pursued using the federal funding now available through the administration's funding program to provide alternatives to current patient treatment

3) The country's HIV pandemic is estimated to costs the United States 100 to 200 BILLION DOLLARS in the next decade.

4) This new therapy does not require chronic administration and therefore (and being a human protein) is potentially non-toxic and therefore is a far superior therapy for patients, as compared to chronic chemotherapy.

5) This more favorable therapy is immunotherapy: which uses currently known (broadly neutralizing human) monoclonal antibodies that binds to and neutralize (kills) the HIV virus.

6) The most potent human monoclonal antibody known today is the antibody produced by a cell line created by BioClonetics; this antibody is known as "Clone 3 antibody".

7) This Clone 3 antibody has been repeatedly tested in 5 independent international laboratories to show that it neutralizes (kills) over 90% of the HIV strains against which it has been tested.

8) With laboratory validation completed, what is needed now are animal trials to

verify that Clone 3 antibody kills the HIV virus in animals; success is expected (and is highly probable) because the Clone 3 antibody is a “human” antibody derived from “human B-cells" [from an HIV+ long-term non-progressor (LTNP)]

9) Once the antibody is tested in animals, it can be tested and used in humans to treat those with HIV; this treatment would be in lieu of chronic chemotherapy (which is toxic to the body) or as a supplementation (adjunctive combined sequential therapy) to reduce the levels of chemotherapy [providing for a drug "holiday", *i.e.*, interruption of chronic continuous chemotherapy with immunotherapy being utilized during the hiatus of ARV use.]

9) Additionally, once animal trials are completed for the Clone 3 Antibody, verifying that the antibody is effective in animal models, the development of an active vaccine against HIV can be initiated.

10) The development of a successful vaccine follows because we also know where on the virus (the binding site on the virus) the antibody attaches to the HIV virus surface; as noted above in paragraph 7, we know that when the antibody attaches to the virus' surface protein, it kills the virus, or prevents (abrogates) the infectivity of the virus.

11) By knowing the binding site (also known as the epitope of the antibody), and knowing the amino acid make-up of the protein to where the antibody attaches on the virus surface protein, a vaccine can be derived that is composed of this epitope (as presented in a vaccine as the immunogenic immunogen) that is a peptide composed of identified amino acids, which are a part of the viral envelope protein coat.

12) Classical immunology teaches that when this epitope is administered (as an immunogenic immunogen) to a individual, the epitope is in fact the vaccine component that causes the immune system—of the individual who is vaccinated—to produce the neutralizing antibody (in the quantity and quality elicited in the vaccination process) and thus an effective vaccination protects the patient from contracting (being infected with) the virus, if indeed—and ever—exposed to HIV.

I am advocating that a portion of the $1.1 billion dollars in funds from The Recovery Act (ARRA) to be used for comparative effectiveness research [CER] which compares treatment strategies to improve health, specifically with regard to evaluation of **passive immunotherapy utilizing broadly neutralizing human monoclonal anti-HIV antibodies**, *e.g.,* Clone 3 Antibody [http://www.bioclonetics.com] directed against HIV gp41, in both adult and especially in maternal-to-child transmission [MTCT] studies, in order to further evaluate the degree of protection afforded to newborn infants by the anti-HIV antibodies in blocking transmission of HIV in HIV+ mother who elect to breast

feed their newborn infants.

These expanded passive immunotherapy human studies are to be conducted in a parallel modality that follow pre-clinical protocols that have been previously published and safely conducted in non-human primate passive immunotherapy studies, which were shown to have been non-toxic and protective in rhesus macaques; as well as human clinical studies that were likewise shown to have been safe, non-toxic and effective which have been published in at least three [3] peer-reviewed journals, *i.e., "Adjunctive Passive Immunotherapy in Human Immunodeficiency Virus Type 1-Infected Individuals Treated with Antiviral Therapy during Acute and Early Infection"*, authored by Hermann Katinger, Ph.D. from Polymun Scientific
[http://www.polymun.at/], and Martin Markowitz, M.D. from the Aaron Diamond AIDS Research Center [ADARC][http://www.adarc.org/], *et al.*, J. Virol. 81(20) Oct 2007 p. 11016.

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